

REMARKS

Claim 1 has been amended in view of U.S. Pat. No. 4,327,076 ("Puglia") to recite that the tablet of the present invention is fat-free. Support for this amendment can be found throughout the specification at, for example, p. 4, lns. 16-24. No new matter has been added by the above amendment. Claim 7 was cancelled in light of the amendment to claim 1. Accordingly, claims 1-5 and 8-13 remain in this application.

Obviousness Rejection

Claims 1-5 and 7-13 were rejected under 35 USC §103(a) as being unpatentable over Puglia in view of U.S. Pat. No. 5,380,541 ("Beyts"). (Paper No. 05122006 at 2.)

For the reasons set forth below the rejection, respectfully is traversed.

Puglia discloses

[57]

ABSTRACT

An improved compressed soft chewable tablet is provided, which may contain an antacid or other active ingredient, has good flexibility, is breakage resistant and disintegrates immediately upon chewing. The tablet of the invention is formed of particles of antacid and/or other active ingredient which are isolated from other ingredients of the tablet, preferably by admixing particles of active ingredient with particles formed of edible fat or oil absorbed on a fat-absorbing material, such as microcrystalline cellulose and blending such particles with one or more tablet bonders; the tablet also includes additional amounts of tablet bonders, flavors and other conventional tableting aids to help in making the tablet more palatable. Upon chewing, the tablet is quickly converted to a smooth creamy non-gritty palatable emulsion.

Abstract

50 resistant and yet may be easily chewed and quickly
disintegrated and dissolved in the mouth. The com-
pressed chewable tablet of the invention includes (a) a
particulate pretreated fat composition formed of an
edible fatty material, a fat-sorbing material having the
55 fatty material sorbed thereon or therein, and one or
more tablet bonders blended therewith, and optionally
one or more antioxidants, flavors and/or colorant; (b) a
pretreated active ingredient composition formed of a
mixture of particles of active ingredient, such as parti-
60 cles of one or a mixture of antacids, and optionally
edible oil, binder, emulsifier, flavor, and colorant, the
particles of active ingredients being coated with the
other components of said pretreated active ingredient
composition; and (c) a pretreated direct compaction
65 tableting aids composition including bonders and op-
tionally flavors, the compositions (a), (b) and (c) being
blended together and the blend being in the form of said
compressed chewable tablet.

Col. 2

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In a preferred embodiment of the compressed chewable tablet of the invention, the active ingredient is comprised of particles of one or more antacids so that the particulate pretreated fat composition (a) will include a fat-sorbing material, preferably microcrystalline cellulose, a fatty material absorbed in the microcrystalline cellulose, optionally a colorant, such as titanium dioxide, optionally an antioxidant, such as butylated hydroxytoluene, optionally an antifatulent, such as simethicone, tablet bonders, preferably tableting sugar and/or dextrose monohydrate, and optionally one or more flavors.

The preferred pretreated active ingredient composition (b) will include particles of one or more antacids, such as calcium carbonate, aluminum hydroxide and/or magnesium hydroxide, and preferably a mixture of all of said antacids, a binder, preferably carboxymethyl cellulose, to help flavor and emulsifier to stick to fat absorbed particles and impart a slippery mouth feel, an emulsifier, such as polyglycerol ester of fatty acids, to help decrease surface tension on the tongue and stimulate salivation, an edible oil, preferably a vegetable oil, to help plating out of the emulsifier on the antacid particles, and flavor.

The preferred pretreated direct compaction tableting aids composition (c) will include tablet bonders, preferably tableting sugar and/or dextrose monohydrate, and flavors and flavor oils.

Col. 3.

The compressed chewable tablet of the invention includes particles of active ingredient, such as antacids, vitamins, laxatives, antifatulents, aspirin, acetaminophen, appetite depressants and the like and will have a non-chalky non-gritty pleasant taste and when exposed to saliva in the mouth converts to an emulsion or colloidal suspension and thus behaves as would a liquid. Also, since the tablet of the invention will disintegrate rapidly

Col. 4

The active ingredient, depending upon the specific properties thereof, will generally comprise from about 20 90 to about 99.9% and preferably from about 92 to about 97% by weight of the pretreated active ingredient composition, and from about 10 to about 50% and preferably from about 15 to about 30% by weight of the final tablet.

Col. 4

The fats or oils used may be of animal, vegetable or mineral origin which are substantially water-insoluble, inert, non-toxic hydrocarbon fats and oils and derivatives thereof and may comprise any of the commonly 55 commercially available fats or oils approved by the Food and Drug Administration and having melting points constant with desired mouth feeling factors, such as melting points ranging from 80° to 110° F. and need 60 not be limited to melting points above body temperature. The fats or oils will be employed in amounts within the range of from about 2 to about 45%, and preferably from about 10 to about 25%, depending upon the properties desired in the final product. Examples of

Col. 4

The fat-sorbing materials (that is, fat-absorbing and- 5 /or fat-adsorbing material) which may be present herein include microcrystalline cellulose, cornstarch, tapioca, dextrin, sucrose, sorbitol, xylitol, mannitol and the like with microcrystalline cellulose being preferred. The fat-sorbing material will be present in the pretreated fat 10 composition in an amount of from about 25 to about 75% and preferably from about 40 to about 60% by weight of said pretreated fat composition and will be employed in a weight ratio of the fatty material of from about 0.625:1 to about 1.815:1 and preferably from 15 about 1:1 to about 1.5:1; the fat-sorbing material will be present in the finished tablet formulation in an amount of from about 10 to about 30% and preferably from about 10 to about 20% by weight.

Col. 5

The edible oil in the pretreated active ingredient 40 composition, which aids in plating out emulsifier on particles of active ingredient, will be present in an amount within the range of from about 1 to about 4%, and preferably from about 1.5 to about 2.5% and may include any of the edible oils disclosed with respect to 45 the fatty materials set out above.

Any emulsifier or surfactant approved for use in foods by the Food and Drug Administration and having an HLB value of 8 and above, may be employed in the pretreated active ingredient composition in forming 50 antacid tablets of the invention in amounts ranging from about 0.05 to about 2.5% by weight and preferably in amounts ranging from about 0.1 to about 1.0% by weight based on the final tablet formulation, and from about 1 to about 4% and preferably from about 1.5 to 55 about 2.5% based on the weight of the pretreated active ingredient composition.

Col. 5

10 The slip agent present in the pretreated active ingredient composition includes cellulose gums, such as carboxymethyl cellulose gum, xanthan gum, locust bean gum, alginic acid, or mixtures thereof and will be present in an amount of within the range of from about 1 to 15 about 5% by weight of the pretreated active ingredient composition, and from about 2.5 to about 3.5%, and preferably from about 0.75 to about 1.5% based on the weight of the finished tablet.

Col. 6.

The following are preferred chewable tablet formulations in accordance with the present invention:

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| | % by Wt. based on pretreated composition | % by Wt. based on total tablet | |
|---|---|--------------------------------------|----|
| I. Pretreated Fat Composition | | | 10 |
| (a) Fatty material (preferably hydrogenated vegetable oil) | 30 to 50 | 10 to 20 | |
| (b) Fat-sorbing material (preferably microcrystal- line cellulose) | 25 to 35 | 10 to 15 | 15 |
| (c) Tableting binders (preferably tableting sugar and dextrose monohydrate) | 20 to 30 | 7.5 to 15 | |
| (d) Flavor | 0.1 to 0.4 | 0.05 to 0.15 | |
| (e) Colorant | 0.05 to 0.4 | 0.1 to 0.3 | 20 |
| (f) Antioxidant | 0.05 to 0.1 | 0.01 to 0.03 | |
| Pretreated | | | |
| II. Active Ingredient Composition | | | |
| (g) Active ingredient (Preferably antacid CaCO ₃ Al(OH) ₃ Mg(OH) ₂) | 50 to 60 15 to 25 15 to 25 | 10 to 15 3 to 6 3 to 6 | 25 |
| (h) Slip agent (preferably carboxymethyl cellulose) | 1.5 to 4 | 0.5 to 1.5 | |
| (i) Emulsifier (preferably polyglycerol ester of fatty acid) | 1 to 3 | 0.25 to 0.75 | 30 |
| (j) Edible oil (preferably hydrogenated vegetable oil) | 1 to 3 | 0.25 to 0.75 | |
| (k) Flavor | 0.2 to 0.5 | 0.05 to 0.15 | |
| Pretreated | | | 35 |
| III. Tableting Aids Composition | | | |
| (l) Tablet binders (preferably tableting sugar and dextrose monohydrate) | 95 to 99.9 | 30 to 40 | |
| (m) Flavor | 1.5 to 5 | 0.1 to 1 | |

40 Col. 7.

EXAMPLE 1

A chewable antacid tablet is prepared as described below from the following three premixes.

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| Premix I (Pretreatment of Fat System) | | Parts by Weight of Total Tablet | 50 |
|--|---|------------------------------------|----|
| 1. | Hydrogenated vegetable oil (Safina II NT) | 16.225 | |
| 2. | Microcrystalline cellulose (Avicel pH 102 - particle size 90 μ) | 12.27 | |
| 3. | Titanium dioxide (colorant) | 0.03 | |
| 4. | Simethicone LVA (antiflatulent) | 1 | |
| 5. | Dextrose monohydrate (Cantab) | 10 | 55 |
| 6. | Artificial vanilla flavor | 0.1 | |
| 7. | Butylated hydroxytoluene (antioxidant) | 0.01 | |

| Premix II (Pretreatment of Antacid Material for Improved Palatability) | | Parts by Weight of Total Tablet | |
|--|--|------------------------------------|--|
| 10 | 8. CaCO ₃ | 13 | |
| | 9. Al(OH) ₃ | 5 | |
| | 10. Mg(OH) ₂ | 4 | |
| | 11. Carboxymethyl cellulose | 0.75 | |
| | 12. Emulsifier (polyglycerol esters of fatty acids) (Santone 8-1-0) | 0.5 | |
| 15 | 13. Vegetable oil (Durkex 500) | 0.5 | |
| | 14. Artificial vanilla flavor | 0.1 | |

| Premix III (Pretreatment of Direct Compaction Tableting Aids) | | Parts by Weight of Total Tablet | 30 |
|---|-------------------------------|------------------------------------|----|
| | 15. Dextrose monohydrate | 23 | |
| | 16. Tableting sugar | 12.5 | |
| | 17. Artificial vanilla flavor | 0.4 | |
| | 18. Peppermint oil | 0.1 | |

Beyts discloses

[57]

ABSTRACT

Synergy is obtained by combining sucralose and a sweet saccharide selected from fructose; glucose; maltose and other glucooligosaccharides; fructose mixed with glucose and/or gluco-oligosaccharides; lactose; isomaltulose; and sugar alcohols.

According to the present invention there is provided a sweetening composition for sweetening ingestible compositions and oral products, the composition consisting essentially of sucralose; a sweet saccharide selected from fructose; glucose; maltose and other glucooligosaccharides; glucose mixed with maltose and other oligosaccharides; fructose mixed with glucose and/or gluco-oligosaccharides, lactose, isomaltulose, and sugar alcohols, and, optionally, a carrier for a sweetening composition; the relative sweetness contribution provided by the sucralose and the sweet saccharide being from 5:1 to 1:5. By the term "sweetening composition", we mean a composition for use in sweetening foodstuffs, beverages etc, e.g. sweetening tablets and granules, concentrates for the beverage industry etc.

(Col. 2.)

EXAMPLE 9

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Peppermint tablet

| | Sorbitol % w/w | Mannitol % w/w | Xylitol % w/w |
|--|-------------------|-------------------|------------------|
| 40 Sucralose | 0.01 | 0.01 | 0.005 |
| Sorbitol ¹ | 98.19 | — | — |
| Mannitol ¹ | — | 98.19 | — |
| Xylitol ¹ | — | — | 98.195 |
| Magnesium Stearate ² | 1.00 | 1.00 | 1.00 |
| 45 Peppermint Durenone ³ sugar free 186292 | 0.80 | 0.80 | 0.80 |

1. Roquette (UK) Ltd.

2. Croxton & Garry Ltd, U.K.

3. Sensensus Taylor Ingredients, U.K.

In making the rejection, the Examiner asserted

Puglia teaches compressed soft chewable antacid tablets that are break resistant and yet fast disintegrating upon chewing. The tablet of Puglia containing antacid particles is mixed with oil or fat absorbed on a fat-absorbing material such as microcrystalline cellulose and tablet binders such as dextrose hydrate, sugars etc (col. 2, lines 46-67, Example 1 & col. 5, lines 22-32). Puglia further teaches addition of sweetening agents such as sugar, saccharin, aspartame etc in the antacid composition (col. 6, lines 40-54). In addition to antacid, Puglia teaches chewable tablets comprising other medicaments such as aspirin, vitamins etc (col. 9). Puglia teaches addition of fats or oil in an amount of 2% to 45%, which includes the claimed percentage of fat (col. 4, lines 53-65). Puglia does not specifically teach particulate dextrose monohydrate.

(Paper No. 05122006 at 2.)

However, the reference teaches blending the dextrose monohydrate with other components of the tablet (col. 8) and thus obviously resulting in a particulate material before being compressed. Puglia fails to teach sucralose of the instant claims.

(Paper No. 05122006 at 2.)

To fill the acknowledged gap, the Examiner relied upon Beyts as follows:

Beyts teaches sucralose containing ingestible compositions such as medicaments, beverages, etc. Beyts teaches that a synergy in obtaining sweetness is observed with sucralose and other saccharides such as glucose, fructose, mannitol, sorbitol, or fructose mixed with glucose. Example 1 of Beyts shows the synergy of sucralose with various sweeteners such as fructose etc., and the list of sweetener blends with sucralose in col. 5, specifically mentions a combination of dextrose monohydrate and sucralose that reads on the instant claimed components. Further example 9 is directed to a peppermint tablet, which meets the description of a chewable tablet. Accordingly, it would have been obvious for one of an ordinary skill in the art at

(Paper No. 05122006 at 3.)

The Examiner concluded as follows:

tablet. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add a synergistic combination of sucralose with other sweeteners such as fructose, dextrose monohydrate, sucrose, glucose etc., of Puglia because Beyts suggests that sucralose is effective in reducing the calorie level in the final preparation of foodstuff, medicaments, beverages etc, and is much sweeter than the sucrose or other sweeteners. Accordingly, one of an ordinary skill in the art would have expected to sweeten the chewable tablet composition of Puglia by adding sucralose together with other sweeteners such that the sweetness intensity of the composition is increased due to the presence of sucralose and yet with low calories.

(*Id.*)

Claim 7 has been cancelled without prejudice. Accordingly any rejection directed to claim 7 is moot and should, therefore, be withdrawn.

As is fundamental, a *prima facie* case of obviousness must be based on facts, “cold hard facts.” When the rejection is not supported by facts, it cannot stand.

It is noted that amended claims 1-5 and 8-13 affirmatively require, among other things, that the tablet is fat-free.

It is appears that Puglia requires fats or oils in amounts within the range of about 2 to about 45%. (See col. 4, lns 61-63.) It is not seen where there is any disclosure of a fat-free formulation in Puglia. This feature provides the unexpected advantages in the claimed invention. As stated in the specification at page 4, formulations with little or no fat are more stable at elevated temperatures, eliminated the need for specially controlled shipping and storage conditions. Fats are susceptible to oxidative and chemical hydrolysis leading to a rancid taste and/or odor.

It is not seen where Beyts discloses or suggests the desirability of including sucralose in a chewable medicament or tablet. At best, Example 9 is a peppermint tablet, which appears to be a succulent tablet. It is not seen where one of ordinary skill in the art would look As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also

providing evidence of the motivating force which would *impel* one skilled in the art to do what the patent applicant has done. Thus, the rejection fails to set forth the required facts and reasoning required to support a *prima facie* case of obviousness. For this additional reason the rejection should be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

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